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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/283,318	03/31/1999	JACK V. SMITH		9827

7590 05/07/2002

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[REDACTED] EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	/L

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/283,318	SMITH, JACK V.
Examiner	Art Unit	
Shanon A. Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 February 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 5,8 and 19-32 is/are pending in the application.

4a) Of the above claim(s) 5 and 8 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 19-32 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

In the amendment filed 2/6/2 in paper no. 14, applicant deleted claims 11-18 and added new claims 19-32. Claims 5, 8, and 19-32 are pending in the application. Claims 5 and 8 remain withdrawn from consideration due to a non-election of invention and claims 19-32 are under consideration. Applicant is reminded to cancel claims 5 and 8. The new claims comprise several patentably distinct inventions that are outside the scope of what was previously examined and a restriction requirement is deemed necessary.

It is noted that the claims have been amended to recite, "without the use of Western Blot, and Thin Layer Liquid Phase methods". These negative limitations cannot be found in the original disclosure. The courts have found that any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). It is suggested that applicant cancel the new matter in order to avoid a rejection under 35 U.S.C. § 112, first paragraph.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 19-22, drawn to a method of detecting the presence of HIV antibodies, classified in class 435, subclass 5.
- II. Claims 23-29, drawn to a method of detecting the presence of HIV antibodies, classified in class 435, subclass 5.
- III. Claims 30-32, drawn to a method of detecting the presence of HIV antibodies, classified in class 435, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions use different reagents, method steps, and indicators to determine the presence of HIV antibodies in a test sample. The method of group I requires the use of IgG antibody, HIV antigen and IgG conjugated to microparticles and an HIV antibody, which are impregnated in three steps. Group II requires the use of HIV antigen conjugated to an enzyme and an indicator substrate complex. These ingredients are not required for group I or III. Group III requires IgG antibody and IgG conjugated to microparticles and does not require the HIV antigen conjugated to microparticles or HIV antigen in group I, or the ingredients of group II. The different reagents and ingredients used in each of the distinct methods denote different mechanisms for determining whether or not HIV antibodies are present in a sample.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, III, the search required for group II is not required for I, III, the search for group III is not overlapping with groups I, II, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SAF
Shanon Foley/SAF
May 6, 2002

James C. Housel
JAMES HOUSEL 5/6/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600